EXHIBIT 1

BlueWillow's Markman Presentation

November 15, 2022

Foley & Lardner LLP

Trutek Corp. v. BlueWillow Biologics, Inc.,

Case No. 2:21-cv-10312 (E.D. Michigan)



(12) United States Patent Wahi

(54) ELECTROSTATICALLY CHARGED MULTI-ACTING NASAL APPLICATION,

(75) Inventor: Ashok Wahi, Hillsborough, NJ (US)

PRODUCT, AND METHOD

(73) Assignee: Trutek Corp., Hillsborough, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 316 days.

(21) Appl. No.: 12/467,271

(22) Filed: May 16, 2009

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Related U.S. Application Data

- (60) Provisional application No. 61/085,855, filed on Aug. 3, 2008, provisional application No. 61/078,478, filed on Jul. 7, 2008.
- (51) **Int. Cl.**A61K 31/198 (2006.01)

 A61K 31/14 (2006.01)
- (52) U.S. Cl. 514/564; 514/643

(10) Patent No.: US 8,163,802 B2 (45) Date of Patent: Apr. 24, 2012

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57) ABSTRACT

A product to reduce and method of reducing the risk of inhalation of harmful substances by applying a formulation composition to a substrate or the skin in close proximity of one or more nostrils. This formulation, when applied creates an electrostatic field having a charge. The electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate close to the skin and a biocidic agent renders microorganisms coming in contact the substrate or skin less harmful.

23 Claims, No Drawings

- "Electrostatically Charged Multi-Acting Nasal Application, Product, and Method"
- 4 asserted claims
 - Claims 1 and 2 (independent claims)
 - Claims 6 and 7 (dependent claims)

Independent Claim 1

I claim:

- 1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
 - a) electrostatically attracting the particulate matter to the thin film;
 - b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
 - c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

Independent Claim 2

- 2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
 - a) electrostatically attracts the particulate matter to the thin film;
 - b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
 - c) inactivates the particulate matter and renders said particulate matter harmless.

contaminants to the nasal passages by capturing the contaminants and keeping them from entering the body. In the present invention, these electrostatically charged nasal application products capture and hold the contaminants including viruses, bacteria, and other harmful microorganisms or toxic particulates, inactivate them dermally outside the body and render them harmless.

'802 patent at 2:2-7

Emergencies of Anthrax lead to the concept of avoidance of inhaling airborne microscopic and sub-microscopic contaminants. It is the intention of the Present Invention to filter and render harmless materials such as anthrax spores, human corona virus, smallpox virus, influenza virus, avian flu virus, swine flu virus, rhino virus, and other biological or chemical elements/toxins/irritants, and the like, prior to their entering the nasal passages.

'802 patent at 3:53-60

VIRAL DISEASES (virus type in brackets)	BACTERIAL DISEASES (bacterial name in brackets)
Chickenpox (Varicella)	Whooping cough (Bordetella pertussis)
Flu (Influenza)	Meningitis (Neisseria species)
Measles (Rubeola)	Diphtheria (Corynebacterium
German measles (Rubella)	diphtheriae)
Mumps (Mumps)	Pneumonia (Mycoplasma pneumoniae,
Smallpox (Variola)	Streptococcus species)
SARS (Human Corona)	Tuberculosis (Mycobacterium tuberculosis)
	Anthrax (Anthracsis bacterium)

'802 patent at 4:5-16

PARTICULATE DISEASES	SOURCE
Psittacosis (Chlamydia psittaci)	Dried, powdery droppings from infected birds (parrots, pigeons, etc.)
Legionnaire's disease (Legionella pneumophila)	Droplets from air-conditioning systems, water storage tanks, etc., where the bacterium grows.
Acute allergic alveolitis (various fungal and actinomycete spores)	Fungal or actinomycete spores from decomposing organic matter (composts, grain stores, hay, etc.)
Aspergillosis (Aspergillus	Fungal spores inhaled from
fumigatus, A. flavus, A. niger)	decomposing organic matter.
Histoplasmosis (Histoplasma capsulatum)	Spores of the fungus, in old, weathered bat or bird droppings.
Coccidioidomycosis (Coccidioides immitis)	Spores in air-blown dust in desert regions (Central, South and North America) where the fungus grows in the soil.

'802 patent at 4:22-38

A formulation of the invention comprises:
water,
at least one quaternary thickener,
a preservative,
a conditioner,
an emulsifier,
a biocidic agent, and
a neutralizing agent added to adjust and achieve a pH in the
range of 5.0 to 6.8.

'802 patent at 4:65 - 5:7

All of the formulations described in TABLE 1-10 representing various embodiments of the Present Invention operate in the manner that was disclosed herein. The same results may be achieved by varying the percentages for the active and inactive ingredients. Varying the percentages for the active ingredients affects the potency of the formulation. Varying the percentages for the inactive ingredients affects the consistency of the formulation. The desired results may be

'802 patent at 10:8-15

Ingredient	Percent Range	Function
Water	72%-88%	Solvent, Moisturizer
Phenoxyethanol	1%	Preservative
Methylparaben,		
Propylparaben,		
Butylparaben,		
Ethylparaben,		
Isobutylparaben		
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	3%-6%	Conditioner, Quaternary
Nonoxynol - 10	2%-4%	Surfactant
Cocodimonium	0.5%-2%	Conditioner, Quaternary
Hydroxypropyl		
Hydrolyzed Keratin		- "
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Polyquaternium - 88	1%-4%	Conditioner, Quaternary
Cetearyl Alcohol,	1%-4%	Emulsifier
Glyceryl Stearate		
Emulsifier,		
PEG - 40 Steamte,		
Ceteareth - 20	0.50/	E1-2
Cetearyl Alcohol,	0.5%	Emulsifier
Dicetyl Phosphate,		
Ceteth - 10 Phosphate Benzalkonium Chloride	0.350/ 10/	Cationia Contamon Bindida
Delination Cities	0.25%-1% 1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.01%-0.05%	Neutralizing Agent

'802 patent at Table 2 (6:18-42)

Claim Construction Disputes

- (1) Indefiniteness under 35 U.S.C. § 112, paragraph 2
 - "Electrostatically attract"
 - "Electrostatically inhibit"
 - "Adequate impermeability"
 - "Renders said particulate matter harmless"
- (2) Trutek's Proposed Constructions

Legal Standards – Indefiniteness

A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims.

Indefiniteness, therefore, like claim construction, is a question of law.

Atmel Corp. v. Info. Storage Devices, Inc., 198 F.3d 1374, 1378 (Fed. Cir. 1999)

Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction.

Exxon Rsch. & Eng'g Co. v. United States, 265 F.3d 1371, 1376 (Fed. Cir. 2001)

Definiteness is to be evaluated from the perspective of someone skilled in the relevant art.

A lack of definiteness renders invalid "the patent or any claim in suit."

Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 902, 908 (2014)

Legal Standards – Indefiniteness

According to the Federal Circuit, a patent claim passes the §112, ¶2 threshold so long as the claim is "amenable to construction," and the claim, as construed, is not "insolubly ambiguous."

We conclude that the Federal Circuit's formulation, which tolerates some ambiguous claims but not others, does not satisfy the statute's definiteness requirement. In place of the "insolubly ambiguous" standard, we hold that a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

[A] patent must be precise enough to afford clear notice of what is claimed, thereby "appris[ing] the public of what is still open to them."

It cannot be sufficient that a court can ascribe some meaning to a patent's claims.

Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901, 909, 911 (2014)

Indefinite Claim Terms

- 1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
 - a) electrostatically attracting the particulate matter to the thin film;
 - b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
 - c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

Trutek's Expert – Dr. Lemmo

Patent claims are often incomprehensible by lay persons because the words and sentence structure are purposed as legal instruments rather than as narratives to be understood by the general public. Claims are long run-on sentences containing words that may be unfamiliar to the layman. Claims are not written with proper English syntax. However, in the case of claims 1, 2, 6, and 7 of the '802 Patent, the words appear to have been given their plain meaning and the clauses are separately enumerated. In my opinion, a person of ordinary skill (i.e., a formulator of pharmaceutical preparations) would be able to read these claims in light of the specification, understand their meanings, and from them he or she would have no difficulty in creating the disclosed embodiment compositions without undue experimentation.

45. I am not an attorney. I understand that the property of a claim being indefinite is a legal determination, which is in the province of the Court. Therefore, I will not use this terminology. Instead, I will opine on whether the disputed claim terms are sufficiently unambiguous to enable one of ordinary skill to understand and practice the inventions set forth in the claims.

Lemmo Declaration at ¶ 45

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Q. Okay. So that was the standard that you applied here, "sufficiently clear and unambiguous to a person of ordinary skill"?

A. Yes, that's correct.
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Lemmo Declaration at ¶ 56

Lemmo Deposition at 139:22-25

The meaning of this phrase is clear and apparent.

The meaning of this term is apparent and unambiguous.

Lemmo Declaration at ¶ 48 ("electrostatically inhibiting") and ¶ 50 ("electrostatically attracting")

Electrostatically Inhibiting and Attracting

- '802 Patent does not provide any objective parameters to allow a POSA to assess whether a formulation operates to "electrostatically attract" and "electrostatically inhibit" harmful particulate matter
 - Amiji Declaration at ¶¶ 32-36
 - No quantitative parameters for electrostatic field
 - What magnitude is necessary to attract oppositely charged contaminants?
 - Distance of electrostatic field from surface?

Some objective standard must be provided in order to allow the public to determine the scope of the claimed invention.

Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1350 (Fed. Cir. 2005)

- "Adequate" is both subjective and a term of degree
- '802 Patent does not provide any objective guidance to POSA as to level of impermeability required or how to assess whether any thin film has "adequate" impermeability
 - Amiji Declaration at ¶ 37

Thus, <u>adequate impermeability</u> is a property of the applied formulation that allows the harmful particles to be held in place for a sufficient time to be inactivated.

Lemmo Declaration at ¶ 37

Determination of adequate permeability is a term of degree, and the material composition to accomplish the intended purpose depends on the desired efficacy. The '802 Patent specification provides examples of the

Lemmo Declaration at ¶ 53

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Q. Now, "sufficient time," that's another relative term; right?

A. Yes. Again, we don't know when an individual will come in contact with a harmful microorganism that's in the airstream. So as I
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Lemmo Deposition at 142:9-13

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11
               Okay. So to the best of your knowledge,
12
     the patent doesn't define how much time is
13
     sufficient to hold the harmful particles in place
14
     to allow them to be inactivated; right?
15
          A. Yeah, at this point that's what I'm
16
     assuming, yes.
17
               Okay. So, I mean, how much time is
18
     sufficient? Is an hour good enough?
20
               THE WITNESS: It's very vague. That's a
     very vague question of how much time. Because as
21
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Lemmo Deposition at 143:11-21

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21
               Okav. So the amount of time that's
     sufficient, it depends on the circumstances;
     right?
24
          A. Yes, I agree with that, yes.
          Q. Okay. So it could depend on where the
     individual who's using the product is located?
2
          A. Yes. If you're in a highly polluted
     area, not necessarily pollution relative to
4
     bacterial pollution but irritants that may be in
     the air, if you happen to visit a place where
6
     people are smoking and you're highly sensitive to
     cigarette smoke or tobacco smoke, that may be a
8
     benefit for a person to possibly reapply. But I
9
     can't say definitely because I haven't done that
10
     testing.
11
          Q. So the amount of time that's sufficient,
12
     it could depend on the environment. It could
13
     depend on the particular sensitivities of the
14
     individual, as well; right?
15
         A. Yes.
16
          Q. It could also depend on the nature of
17
     the material that's in the air; right?
18
             Yes.
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Lemmo Deposition at 144:21 – 145:18

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15
               Okay. So the impermeable barrier is a
16
     result of the adhesive and cohesive properties of
17
     the formulation?
18
             That's how I interpret it, yes.
19
          O. And those adhesive and cohesive
20
     properties can be different depending on the
21
     ingredients and the percentages of those
22
     ingredients in the formulation; right?
23
          A. Yes.
24
             Which in turn can impact the level of
25
     impermeability?
1
               Probably, yes.
          Α.
2
             And the ability of -- or the amount of
3
     time that the thin film acts as a barrier?
4
               Correct. But these would all be tests
          A .
5
     performed on the product beyond the scope of the
     patent. So, in other words, what I reiterated
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Q. Okay. But just even more simply, the
patent doesn't describe the results of any testing
of that nature of any of the formulations that are
listed; right?

A. No.
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Lemmo Deposition at 149:10-14

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Q. So the -- to achieve the adequate
impermeability recited in the claims, that's also
going to depend on how the product is applied by
the user?

A. I would assume so, yes.
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Lemmo Deposition at 168:18-22

Lemmo Deposition at 147:15 – 148:6

Renders Said Particulate Matter Harmless

- Whether something is "rendered harmless" is subjective and context dependent, depending on the nature of the harmful particulate matter, the formulation, and the individual
 - Amiji Declaration at ¶ 38
 - Wide range of harmful particulate matter disclosed and claimed
 - What amount of harmful particulate matter must be held to render it harmless?
 - No objective criteria to allow POSA to assess whether the harmful particulate matter is rendered harmless

In other words, a given embodiment would simultaneously infringe and not infringe the claims, depending on the particular bacteria That is the epitome of indefiniteness.

Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1384 (Fed. Cir. 2003)

Renders Said Particulate Matter Harmless

```
25
                So right at the top of this page, you
1
     state that, "Determination of adequate perm
     ability is a term of degree"; right?
             Yes.
4
               And that in turn is going to depend on
     the desired efficacy?
          A. Yes.
               And the desired efficacy could also
8
     depend on the nature of the harmful particles to
     be captured by the formulation and infection
10
     inhibited by?
11
          A. Yes.
14
     grammar. But just for clarification, my
15
     understanding, again, it depends on, in a
16
    microbiological standpoint, the type of organism,
17
     the quantity of organism that a person would be
18
     coming in contact with.
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Lemmo Deposition at 160:25 - 161:18
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Okay. And so using that example then,
     if we're in allergy season where there's a high
9
     amount of allergens in the air, you might need a
10
     formulation that has increased adhesive and
11
     cohesive properties with a more impermeable
12
     barrier in order to sufficiently capture and hold
13
     those particles and preventing them from -- or
14
     inhibiting them from infecting the individual;
15
     right?
16
          A. Or you may want to apply the product
17
     more frequently. So I --
18
          O. And that would be because the adhesive
19
     properties would impact how long the formulation
20
     stays as a thin film?
21
          A. Well, how long it's going -- well, how
22
     much you're coming in contact with -- you know,
     some people come in contact with very polluted
24
     environments, but on an average basis -- again,
     this is not a prescription, but on an average
1
     basis a product that you have sold
     over-the-counter is something that's left up to
3
     the individual to make a judgment as far as how
     much and how often they use the product.
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Lemmo Deposition at 163:7 – 164:4

[T]he claim construction inquiry . . . begins and ends in all cases with the actual words of the claim.

Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998)

[T]he claims of a patent define the invention to which the patentee is entitled to exclude.

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)

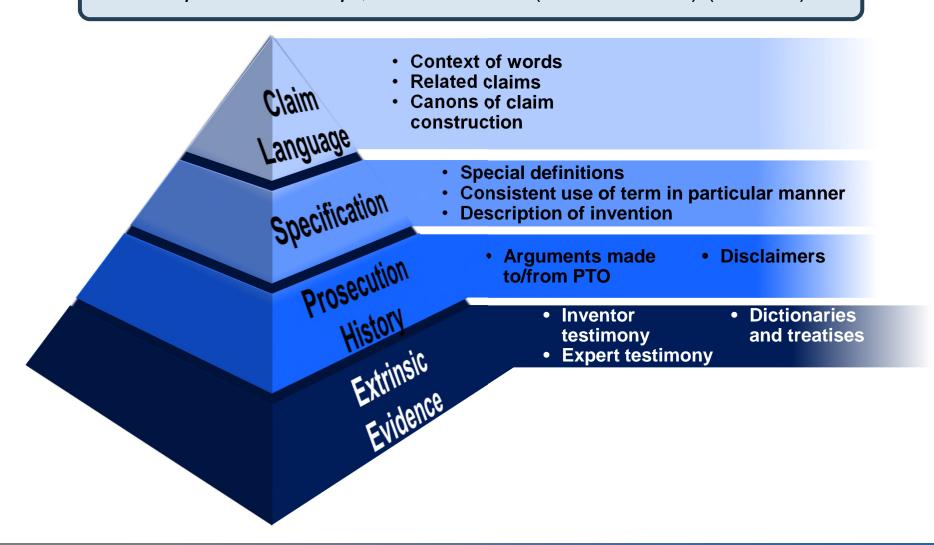
[T]he words of a claim "are generally given their ordinary and customary meaning."

We have made clear . . . that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.

In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.

Philips v. AWH Corp., 415 F.3d 1303, 1312-14 (Fed. Cir. 2005) (*en banc*)

Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc)



[W]hen a word is changed during prosecution, the change tends to suggest that the new word differs in meaning in some way from the original word.

Ajimototo Co., Inc. v. Int'l Trade Comm'n, 932 F3d 1342, 1351 (Fed. Cir. 2019)

[T]his court has consistently adhered to the proposition that courts cannot alter what the patentee has chosen to claim as his invention, that limitations appearing in the specification will not be read into claims, and that interpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.

Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989)

The Markman decisions do not hold that the trial judge must repeat or restate every claim term in order to comply with the ruling that claim construction is for the court. Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy.

U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997)

Trutek's Proposed Constructions

CLAIM 1

PATENT CLAIM LANGUAGE	INTERPRETATION
A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a	Claim 1 is a method claim, which recites preventing an individual from becoming infected from inhaling harmful airborne contaminant particles.
thin film, said method comprising:	A formulation, which exhibits a static electrical charge, is applied to the individual's nostrils, and it forms a statically charged thin film thereon.
a) electrostatically <u>attracting</u> the particulate matter to the thin film;	The formulation's electrostatically charged thin film attracts oppositely charged harmful particles.
b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,	The thin film formulation is designed to adhere to the skin or tissue of the nostrils and to be impermeable. The thin film having a electrostatic charge captures and holds the oppositely charged harmful particles (that
	were attracted to it) in place.
c) <u>inactivating</u> the particulate matter by adding at least one ingredient that would render said particulate matter harmless.	The formulation contains at least one ingredient that inactivates the captured harmful particles and renders one or more of them harmless by killing or inactivating them

Trutek's Proposed Constructions

CLAIM 2

PATENT CLAIM LANGUAGE	INTERPRETATION
A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:	A formulation, when applied to a person's nostrils, forms a thin film therein and prevents that person from becoming infected from inhaling harmful airborne contaminant particles. The formulation contains at least one cationic agent. A cationic agent produces a positive electrostatic charge. The formulation also contains a biocide.
a) electro statically <u>attracts</u> the particulate matter to the thin film;	Oppositely statically charged harmful particles are attracted to the formulation's thin film. The thin film is positively charged (cationic), and most harmful particles are negatively charged.
b) <u>holds</u> the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,	The thin film formulation is designed to adhere to the skin or tissue of the nostrils and to be impermeable. The thin film having a electrostatic charge captures and holds the oppositely charged harmful particles (that were attracted to it) in place.
c) <u>inactivates</u> the particulate matter and renders said particulate matter harmless.	The biocide in the formulation inactivates the captured harmful particles and renders them harmless.

Trutek's Proposed Constructions

CLAIM 6

PATENT CLAIM LANGUAGE	INTERPRETATION
The formulation of claim 2 wherein	This claim depends from claim 2. All of the features and limitations of claim 2 are incorporated by reference into this claim.
the at least one cationic agent is Benzalkonium Chloride.	The "at least one cationic agent" referred to in claim 2 is Benzalkonium Chloride, which is a known cationic agent.

CLAIM 7

PATENT CLAIM LANGUAGE	INTERPRETATION
The formulation of claim 2 wherein	This claim depends from claim 2. All of the features and limitations of claim 2 are incorporated by reference into this claim.
the at least one biocidic agent is Benzalkonium Chloride.	The "at least one biocidic agent" referred to in claim 2 is Benzalkonium Chloride, which is a known biocidic agent.

Independent Claims 1 and 2

- 1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
 - a) electrostatically attracting the particulate matter to the thin film;
 - b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
 - c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

- 2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
 - a) electrostatically attracts the particulate matter to the thin film;
 - b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
 - c) inactivates the particulate matter and renders said particulate matter harmless.